NHS
Blood and Transplant

# Board Meeting in Public
# Tuesday, 28 November 2023

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| **Title of Report** | Clinical Governance Report | **Agenda No.** | 4.1.2a |
| **Nature of Report** | ☒ Official | ☐ Official Sensitive | |
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| **Lead Executive** | Denise Thiruchelvam, Director of Nursing | | |
| **Non-Executive Director Sponsor** | Professor Charles Craddock | | |
| **Presented for** | ☐ Approval<br>☒ Assurance | ☒ Information<br>☒ Update | |

**Purpose of the report and key issues**

This paper summarises the Clinical Governance Committee (CGC) meeting held on the 17th of November 2023. Key issues:

- There are four open and one closed SIs in NHSBT during this reporting period. Two new SIs were recorded; the first incident related to a patient who had a transfusion reaction following receiving incompatible blood and required intervention to treatment the reaction. The second incident related to malaria testing machine fault was discovered. A lookback exercise of this incident identified three blood units with inconclusive results, which were issued and transfused to patients. Fortunately, no harm to patients occurred.
- NHSBT revisited its position in relation to Montgomery consent requirements for blood and plasma donors. The review highlighted that several actions have been taken by NHSBT and any possible risk associated with the case has been reduced to the lowest level within the donation pathway. Therefore, the review committee and the ET accepted the recommendation that NHSBT is to continue with the current position.
- The Serious Hazards of Transfusion (SHOT) annual report provided assurance that blood donations continue to be safe. NHSBT are engaged in several workstreams related to SHOT recommendations particularly related to training and education. Furthermore, the annual Epidemiology review provided assurance on blood, tissues and organ donors and transfusion transmitted infections. The number of infections and donor compliance is similar to 2021; the implementation of FAIR has had no detrimental impact on safety; and the introduction of anti-HBc screening has resulted in added protection for blood recipients.

| **Previously Considered by** | |
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| N/A | |
| Recommendation | The Board is asked to note the report and discuss where relevant. |

**Risk(s) identified (Link to Board Assurance Framework (BAF) Risks)**

Principal Risk-01 Donor / Patient Safety & Principal Risk-06 Failure to Monitor Clinical Outcomes.

**Strategic Objective(s) this paper relates to:** [Click on all that applies]

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| ☒ Collaborate with partners | ☐ Invest in people and culture | ☐ Drive innovation |
| ☐ Modernise our operations | ☒ Grow and diversify our donor base | |

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| **Appendices:** | None |

## 1. Serious Incidents (SIs)

*1.1 Summary*

There are four open and one closed SIs in NHSBT, and two of these are new SIs recorded during this period **(QI36303 and QI36772)**.

1.2 *New SIs during this reporting period – Two new SIs recorded during this period* (both reported to the Board previously):

1.2.1 Blood Supply **SI QI36303** – Malaria antibody screen machine (DS2) was found to be faulty. The error could have caused positive malaria testing results to erroneously be shown as negative.

A lookback exercise identified 20 samples which could be viewed as being close enough to the expected cut off value as warranting retesting. Of these 20, three donations have inconclusive results associated that should have been discarded but instead issued to hospitals with negative results. The impacted hospitals have been asked to review their patients and fortunately no patient harm has been identified.

The investigation was completed, and an action plan was agreed and is currently being implemented.

1.2.2 Clinical Services **SI QI36772** - This incident is related to a patient who experienced severe haemolytic transfusion reaction following transfusion of incompatible blood units. The laboratory was given a verbal advice by NHSBT medical consultant to supply antigen negative units, which was recorded on paper and attached to the laboratory information management system (Hematos), but not appended/linked to the correct sample.

An immediate action was taken to ensure that the person responsible for cross-matching, promptly input any verbal communication from the consultant into Hematos. A long-term electronic solution, to ensure all relevant information is available during cross-matching, is also being explored. This incident is also linked to a known risk in relation to the lack of electronic and central repository for clinical advice.

*1.3 Open SIs* - Two SIs discussed previously are still open:

1.3.1 Clinical Services **SI QI35832** –It is in relation to a sickle cell patient who received 10-15 ml air into their circulation (an air embolism) during Red Cell Exchange due to an error in setting up the apheresis machine. The patient experienced shortness of breath and chest pain but recovered and completed treatment. The investigation has completed, and an action plan is being implemented. Key casual factors included lack of standardised training and lack of alerting system of air within the blood coil warmer attachment. The closure report is being completed.

1.3.2 Due to the involvement of external organisations, the Organ and Tissue Donation and Transplantation (OTDT) **SI INC6524** is still awaiting the external, and NHS England led, closure report. NHSBT has completed its internal investigation regarding this Never Event incident, where unintentional ABO-mismatched solid organ transplantation occurred.

1.4 *Closed SIs and shared learning*

1.4.1 Clinical Services **SI QI33203** - This SI is regarding a patient who developed sepsis after receiving Plasma Exchanges (PEX) treatment via a central line in one of the Therapeutic Apheresis Units. After the meeting, this SI was closed. The closure report and shared learning will be discussed in the next meeting and included in the next report.

## 2. Clinical Risk

A deep dive of Principal Risk 06, Improvement in clinical outcome of patients, was performed. Since last review, four risks contributing to improvement in patient outcome were identified: innovations in therapeutic apheresis and peripheral blood stem cell collection; opportunities to improve clinical outcomes for stem cell patients; blood usage; and organ and tissue transplantation outcomes. It was agreed to revise the principal risk articulation to capture NHSBT intention to reduce health inequalities and focus the contributing risk management on key priority areas. It was also acknowledged that mitigation actions will be long term that will take time to define clearly and reduce the risk.

## 3. Clinical Audit

3.1 **Re-audit on the NICE quality standard 138 -** The National Clinical Audit team undertook this national clinical, which aimed to evaluate local evidence of compliance with four NICE Quality Standards for Blood Transfusion. The audit highlighted little improvement since the previous audit in 2021. It showed that only 59% of patients with iron deficiency anaemia (IDA) were treated with iron before surgery; one out of three eligible patients undergoing surgery received tranexamic acid; two out of three eligible patients receiving elective red blood cell transfusions did not have their haemoglobin levels checked after being transfused; and only one in three patients were given an information sheet about the risks, benefits and alternatives to transfusion. The National Clinical Audit team aims to understand challenges to guidelines adherence and share lessons learned across the NHS to support adherence.

3.2 **Re-Audit of Follow-Up of Pre-Cut DSAEK Grafts from Filton Eye Bank (AUD4892)** - This internal clinical audit aimed to review the outcomes of grafts issued since re-launch of the pre-cutting service in December 2022 and use of Optical Coherence Tomography (OCT) imaging technology. The audit highlighted that graft outcomes were improved. It hence provided **substantial** assurance that the performance of pre-cut grafts supported by the OCT imaging is overall satisfactory. Further actions will be implemented including longer-term follow up of the graft outcomes and addressing some of the feedback provided by the surgeons.

3.3 **Substitutions in Orders of Rare Red Cell Units Audit (AUD4762) -** This internal clinical audit aimed to determine if the updated guidance for rare red blood cell product substitutions was being adhered to. The audit indicated that blood substitutions were appropriately issued and hence provided a **substantial** assurance**.**

## 4. Safety Policy Update

4.1 **The Serious Hazards of Transfusion (SHOT) annual report –** This report provided assurance that blood donations are continue to be safe. Rare complications for donors were highlighted including vasovagal events and needle insertion pain after 12 months. Recipient hemovigilance

reporting highlighted key issues; pulmonary complications, delays in transfusion and ABO incompatibility event (rare, but are never events).

Several recommendations were proposed to safe transfusion including: the use of system-based investigation of incidents with adequate numbers of trained staff supported by technology and automation, and appropriate management of anaemia with effective patient blood management and safe transfusion decisions.

NHSBT are engaged in a number of workstreams related to SHOT recommendations particularly related to training and education and linking in with Transfusion 2024 and Patient Safety Incident Response Framework (PSIRF).

4.2 **Annual Epidemiology Review –** This year review provided assurance on blood, tissues and organ donors and transfusion transmitted infections. Key highlights included: the number of infections and donor compliance is similar to 2021; the implementation of FAIR has had no detrimental impact on safety; the introduction of anti-HBc screening has resulted in added protection for blood recipients, although it has had significant impacts on donors, particularly those from countries where hepatitis B is endemic; horizon scanning for new and emerging infections continues in conjunction with UK Health Security Agency (UKHSA); and hepatitis E peaked in summer 2023, but this high level was seen in 2019.

## 5. Directorate CARE updates

5.1 **Impact of Montgomery Consent Requirements -** The Montgomery case recognised exceptions to the requirement for full disclosure of risks to patients, except in certain defined circumstances. Impact of Montgomery consent requirements across NHSBT was reviewed in 2016, and gaps were addressed. Due to the ongoing consent work in Blood Supply Directorate, it was decided to revisit NHSBT position in relation to Montgomery consent requirements for blood and plasma donors. The review highlighted that several actions have been taken by NHSBT and any possible risk associated with the case has been reduced to the lowest level within the donation pathway. Therefore, the review committee and the Executive Team (ET) recommended that NHSBT is to continue with the current position. The case of Montgomery related to a patient and the applicability of Montgomery to volunteers has not been tested in court and is therefore unclear/ not known. Other work in relation to consent documentation will continue.

5.2 **Clinical Research proposal on immortalised cell lines -** NHSBT considered a research application submitted by a commercial company, Scarlet Therapeutics, requesting buffy coats for use in the production of immortalised cell lines. The production of immortalised cell lines has ethical and consent considerations, due to their immortal status and potential for considerable commercial gain. NHSBT will be acting as a contract supplier and tester of the material using established procedures compliant with Blood & Safety Quality Regulations (BSQR). Scarlet Therapeutics will be responsible for consenting participants and all subsequent activity. NHSBT has decided is to only supply material for pre-clinical use at this stage as further information and assurances are required prior to proceeding to later clinical phases of evaluation.

5.3 **A proposal by the NHS Cord Blood Bank (CBB)** regarding informing donor mothers and their General Practitioners of historical and future results of Group B Streptococcus (GBS) identified in cord blood collections. Such results are important to inform management of subsequent

pregnancies of the mother, as there is a risk of GBS disease of the neonate. Nine historic cases with positive results are identified. These mothers will be contacted by the clinical team via their GP. It was acknowledged that, if affected, mothers may question why the result was not communicated with them earlier.

5.4 **FAIR III Recommendations in tissue and cell donors** - A change control notification was issued in September with a six-week implementation period to allow changes to the donor questionnaire to be made and relevant training to be rolled out. Changes will go live on the Joint UK Professional Advisory Committee (JPAC) from 15th November 2023. Tissue and Eye Services (TES) team is not able to go live for the deceased tissue donors until 2024 due to ongoing IT projects that require completion first. This issue has been reported to the Safety of Blood, Tissues and Organs (SaBTO) and Department of Health and Social Care (DHSC).

5.5 **Children at donor sessions new Policy –** A new policy on children at blood donor sessions was implemented in September 2023. Several complaints have been received from donors who were not aware of the change in the policy and those who are unhappy with the policy. These complaints were expected and are being monitored. Messages through texts and emails were sent out to donors in advance of the changes. Further information will be included within the Donor Newsletter this month. It was highlighted that a review of the decision-making process around this policy and how this was communicated to stakeholders and donors will take place.

## 6. Effectiveness Review

An effectiveness review of the Clinical Governance Committee is proposed by the Company Secretary. All agreed that the review should be undertaken as soon as possible, however the proposed questionnaire for members and attendees was felt to be excessively long. The chair agreed to review the questionnaire with the secretariat before circulation.